

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, CVS INDIANA, L.L.C.,
CARDINAL HEALTH, INC., RITE AID
OF MARYLAND, INC. *dba* Rite Aid Mid-
Atlantic Customer Support Center, Inc.,
WAL-MART STORE EAST, LP *dba* Wal-
Mart Pharmacy Warehouse #46,
KROGER LIMITED PARTNERSHIP II,
McKESSON CORPORATION,
WALGREEN EASTERN CO., INC.,
KROGER LIMITED PARTNERSHIP I,
and H. D. SMITH WHOLESALE DRUG
CO.,

Defendants.

Civil Action No. 3:17-cv-01665
Judge: David A. Faber

**DEFENDANT AMERISOURCEBERGEN DRUG CORPORATION'S NOTICE
REGARDING NON-PARTY FAULT UNDER W.VA. CODE § 55-7-13d(a)(2)**

INTRODUCTION

Defendant AmerisourceBergen Drug Corporation ("ABDC") hereby submits this Notice pursuant to W. Va. Code § 55-7-13d(a)(2). ABDC will amend this Notice if and as appropriate to reflect its receipt through discovery or otherwise of information deemed sufficient to indicate that any particular entity is or is not wholly or partially at fault with respect to the Plaintiff's

(sometimes “the County”) allegations of harm or the recovery sought in this case. Neither this Notice or future amendments to it may be construed as waiving ABDC’s individual ability and right to argue and present evidence that non-parties are the sole and proximate cause of any and all complaints made and injuries and damages claimed by Plaintiff.

NOTICE

As provided in W. Va. Code § 55-7-13d(a)(2), “[f]ault of a non-party shall be considered if ... a defending party gives notice no later than one hundred-eight[y] days after service of process ... that a non-party was wholly or partially at fault. . . and provide the “best identification of the nonparty which is possible under the circumstances. . .” If litigation of the Plaintiff’s claims in this case concerning the opioid epidemic proceeds, it will necessarily require an assessment of the conduct of all entities who were involved in prescribing, dispensing, manufacturing, regulating, and using opioid medications that came into the County during a particular relevant time frame.¹ Thus, the number of potentially fault-bearing parties is inestimable, but very large.

Accordingly, ABDC hereby notifies the Court and all currently named parties that if any diversion² is determined to have occurred in or into the County and if FAULT is eventually to be allocated in order to apportion any reimbursement allowed to the County for its budgeted expenditures made to perform its public duties as a consequence thereof, then entities in the

¹ See Transcript of Proceedings, *Cty. Comm’n of McDowell Cty. v. McKesson Corp.*, et al., Civ. Action No. 1:17-CV-00946, at 30:17–23 (S.D.W.V. Mar. 28, 2017) (THE COURT: “If, if you’re proving an, an opioid epidemic here, wouldn’t you have to have all of the players in that epidemic in court which would include the pharmacies and the distributors and everybody else rather than just the . . . distributors and one doctor who prescribed some of the drugs?”).

² “Diversion” is defined by the WV Board of Medicine in its Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (9 September 2013) as “the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.”

categories described below clearly must be wholly or partially at fault for such diversion and that fault must be determined and allocated to them.

As to whom those fault-bearing entities are, ABDC is unable to identify specific non-parties at this time for the following reasons. First, because of the vague and conclusory nature of Plaintiff's allegations and the complete absence of any factual information or allegations or information in the Complaint that indicate which pharmacies, doctors, or other entities actually diverted any controlled substances from authorized to unauthorized entities for illegal misuse or abuse. There is no allegation that ABDC distributed to unauthorized entities and Plaintiff acknowledges many diverters generally, but Plaintiff does not identify any.

Second, no discovery has been accomplished in this case. ABDC respectfully submits that the purpose of WV Code §55-7-13d(a)(2) is not served by indiscriminant identifications of nonparties without sufficient, specific information upon which to base such identifications. Thus, without any discovery, the "best identification possible under the circumstances" is the provision of the categories that follow.

Plaintiff's Complaint utterly fails to provide factual allegations to support its generic, conclusory, group pled allegations that target only ABDC and the other defendants with no identifying detail whatsoever regarding all the other participants in the closed legal system relating to controlled substances; without providing any factual allegations to support those generic, conclusory allegations; and without appropriate cognizance of the intervening criminal conduct that is the clear proximate cause of the alleged opioid epidemic. ABDC cannot accept and certainly cannot cure these fatal deficiencies, but will, if necessary, as information becomes available, make every reasonable effort to comply with the intent of W.Va. Code §55-7-13d(a)(2)

by identifying and seeking the apportionment of “fault” to all those who may be found to have failed to satisfy a retrospective assessment of their good faith efforts to meet their responsibilities.

All of the entities included within each of the categories identified below have a professional and/or legal duty to protect against diversion. While ABDC believes and asserts that the vast majority of those entities (and the persons who work within them) have conducted themselves honorably and have endeavored in good faith to comply with applicable laws, regulations, and professional responsibilities, there may be entities within each category who have intentionally transferred controlled substances from authorized to unauthorized entities for the purpose of abuse or misuse, which is a criminal act. In the case of federal or state agencies, ABDC does not necessarily believe that they acted with intent to divert controlled substances; however, if proof of a good faith effort to comply with statutory, regulatory, and professional responsibilities may nevertheless be held to constitute actionable negligence or otherwise culpable conduct then they too may inevitably be found “at fault” for the opioid abuse epidemic and its sequelae. If, for example, although well intended, the FDA or DEA failed in meeting their obligations under the federal Controlled Substances Act, and such well-intended, good faith effort does not relieve them of “fault,” then such fault must be apportioned.

ABDC, however, lacks the authority, necessary information, ability to investigate, and knowledge that are necessary in order to specifically identify those entities wholly or partially at fault, in the context of Plaintiff’s allegations. Because this case has been stayed and no discovery has been completed, ABDC has been unable to undertake measures such as obtaining potential discovery from the DEA, the West Virginia Board of Pharmacy, the West Virginia Attorney General, the WV DHHR, the WV Bureau of Medical Services, various other law enforcement agencies that have jurisdiction, government and private officials and entities,

pharmacies, doctors, and other sources such as might provide sufficient support for a specific allegation of diversion to be made.

ABDC does not believe or assert that any of its customers are known to it this time to have engaged in diversion of controlled substances, but cannot say that it is not possible that some may have done so without its knowledge.

IDENTIFICATION OF CATEGORIES OR ENTITIES

Accordingly, ABDC respectfully identifies the following categories of non-parties who are wholly or partially at fault:

I. Pharmacies

ABDC distributes controlled substances only to pharmacies holding valid licenses and registrations from the state and federal government authorizing them to dispense such medications. Plaintiff's Complaint alleges that ABDC failed to report suspicious pharmacy orders to the DEA and West Virginia Board of Pharmacy ("BOP"). Implicit in this allegation is the further allegation that pharmacies within the County placed "suspicious" orders that were honored by ABDC and that controlled substances delivered in accord with those orders were diverted by those pharmacies in violation of their statutory, regulatory, and professional obligations. But Plaintiff does not identify any such pharmacies, although it must know of them in light of its allegations.³

II. Pharmacists

ABDC anticipates that discovery may reveal the names of specific pharmacists and pharmacists-in-charge of the above-described pharmacies who diverted (or themselves abused)

³ If and when Plaintiff admits that any particular pharmacy in Cabell County (or elsewhere) did not place suspicious orders, the Distributor Defendants will consider amending this Notice accordingly.

controlled substances. If litigation of Plaintiff's generic, conclusory allegations ever leads to the identification of specific instances of such diversion, the individual pharmacies and pharmacists involved will be at fault, must be apportioned, and this Notice will be amended to reflect them.

III. Prescribing Practitioners

Pharmacies and pharmacists are legally prohibited from dispensing controlled substances except pursuant to a valid prescription from a duly licensed and registered medical professional who issued the prescription "in the usual course of professional practice for a legitimate medical purpose." To the extent that opioid medications (or other controlled substances) delivered by ABDC to such pharmacies and pharmacists within the County (or in other counties but that came into the County) were dispensed pursuant to a prescription that was not so issued, the prescribing practitioner's conduct was unlawful and/or a breach of professional duty and/or criminal and/or negligent and/or a diversion, and their fault must be apportioned.⁴

IV. Individuals Involved in Illegal Drug Sales

Upon information and belief, the most significant source of diversion of controlled substances is patients who obtain controlled substances legally then sell or give them to others for misuse; further, many persons known or knowable to the County's and state's law enforcement have been involved in the illegal sale of opioid medications, heroin, fentanyl, carfentanil, and/or other illegal drugs within or into the County. Any harm the County may have experienced from illegal drug abuse was caused, wholly or in part, by illegal drug dealing activities within or into the County. ABDC cannot ascertain who these individuals are until we discover and assess the County's (and state's) law enforcement and prosecutorial information;

⁴ If and when Plaintiff admits that any medical provider did not prescribe controlled substances other than for a legitimate medical purpose, the Distributor Defendants will consider amending this Notice accordingly.

another source that may identify such individuals will be relevant searches of the West Virginia BOP CSMP database. If the litigation proceeds and such persons are identified, this Notice will be amended accordingly.

V. Pharmaceutical Manufacturers

Pharmaceutical companies develop, test, manufacture, label, warn, instruct, advertise, market, and promote prescription opioid medications. To the extent the opioid medications delivered by ABDC to pharmacies within the County were improperly prescribed and/or dispensed by reason of inadequate instructions or warnings or false or misleading advertising and promotion by the manufacturers, their actions or omissions caused or contributed to the harm alleged by Plaintiff and their fault must be apportioned. (NOTE: the FDA may also bear some of the fault for inadequate, untimely, or incorrect labels, instructions, and especially warnings.)

VI. Non-party Wholesale Pharmaceutical Distributors

ABDC is only one of the approximately 300⁵ wholesale distributors who are duly licensed, registered, and authorized to distribute controlled substances to pharmacies in West Virginia and into the County. To the extent that opioid medications were improperly dispensed by such pharmacies, as alleged by the Plaintiff, and those medications were supplied in whole or in part to such pharmacies by wholesale distributors other than ABDC, those other distributors may have done so culpably and, if so, their fault should be apportioned. Absent discovery from the WV BOP and the pharmacies themselves, ABDC cannot identify such entities.

VII. Federal and State Agencies That Pay for Opioids

ABDC has no contact with patients. By reason of the federal Health Insurance Portability and Accountability Act ("HIPAA"), ABDC does not know, and is prohibited to find

⁵ Anecdotal information obtained informally from the WV BOP.

out, what practitioner prescribed opioid drugs or other controlled substances for a patient at what dosage, in what quantity, at what time, with what regularity, for which patients with what medical problems, or what pharmacy or pharmacies or hospitals or clinics dispensed them. Upon information and belief, Medicare, Medicaid, and the state and federal agencies that administer these and other government programs, had access to or maintained data reflecting which doctors mis- or over prescribed opioid medications and which patients misused them, but failed to act appropriately on that information and continued to pay for those drugs to be provided. If Plaintiff's Complaint's generic, conclusory, group pled allegations go forward, such entities may be "at fault" and must be apportioned.

VIII. Other Federal, State, and Local Government Entities

ABDC is registered by the DEA and licensed by the West Virginia BOP as a wholesale distributor of controlled substances; both of these agencies have enforcement and investigatory authority, and are vested with power commensurate with their responsibilities. ABDC fulfills orders for controlled substances from pharmacies that are also registered by the DEA and duly licensed by the BOP. The DEA regulates controlled substances under the federal Controlled Substances Act, including establishing annual production quotas for Schedule I and II controlled substances, including opioid medications. The BOP administers and enforces the West Virginia Controlled Substances Act, including the authorization, inspection, and regulation of manufacturers, distributors, pharmacies, and pharmacists. It also has the capability and authority to identify possible diverting doctors/medical practitioners, pharmacies/pharmacists, and patients, and to take action itself or refer to other agencies (such as the WV Board of Medicine) for action those it designates as potential diverters.

The West Virginia Board of Medicine, West Virginia Board of Osteopathic Medicine, West Virginia Board of Dentistry, and the West Virginia Board of Examiners for Registered Professional Nurses, among others, are responsible for licensing and regulating practitioners who prescribe opioid medications within or into the County.

The West Virginia State Police, the Cabell County Sheriff's Department, and the police departments of municipalities in Cabell County are responsible for enforcing the laws related to illegal drug sale and use. The Bureau for Medical Services ("BMS") of the West Virginia Department of Health and Human Resources administers the West Virginia Medicaid Program with the goal "to improve the quality of care and health outcomes for West Virginia Medicaid members by assuring that the medications prescribed for them are appropriate, medically necessary, and not likely to result in adverse medical effects" (emphasis added). BMS requires, *inter alia*, that prior authorization be obtained through the Rational Drug Therapy Program (the "RDT") of the WVU School of Pharmacy before opioids prescribed for chronic pain are reimbursable. The West Virginia Public Employees Insurance Agency (the "PEIA") likewise requires prior authorization through the RDT for certain opioid medications before the medications are reimbursable. As the PEIA's website states, "[a]ll prior authorization requests must be reviewed annually." Other federal and state programs that provide reimbursement for opioid medications may similarly seek to ensure the medical necessity of prescription opioids.

As a wholesale distributor, ABDC does not have contact with patients. By reason of HIPAA, ABDC does not know, and is prohibited to find out, what practitioner prescribed opioid drugs for a patient or what pharmacy dispensed them, or with what regularity or in what dosage amounts. Numerous federal, state, and local agencies had and have knowledge of opioid prescribing, dispensing, and use practices, as well as illegal drug dealing, and had authority to

enforce the law. Their failure, individually and collectively, to take timely and effective enforcement action caused or contributed to any complaints, harm, injuries, and damages alleged by Plaintiff and their fault must be allocated.⁶

Dated this the 18th day of September, 2017.

Respectfully submitted,

**AMERISOURCEBERGEN DRUG
CORPORATION**

By Counsel

/s/ A. L. Emch

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⁶ Governmental entities may be “wholly or partially at fault” under W. Va. Code § 55-7-13d, whether or not they enjoy immunity from suit or otherwise cannot be named as a party defendant.

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CERTIFICATE OF SERVICE

I, Alvin L. Emch, counsel for Defendant AmerisourceBergen Drug Corporation, do hereby certify that on 18 September 2017, I served the foregoing *Defendant AmerisourceBergen Drug Corporation's Notice Regarding Potential Nonparty Fault Under W.Va. Code § 55-7-13d* via the CM/ECF system, which will provide notification and a copy of the filing to all counsel of record.

/s/ A. L. Emch

A. L. Emch (WVSB # 1125)